

Attorney Docket No.: DC-0301  
Inventors: DeLeo, Joyce A.  
Serial No.: 10/521,167  
Filing Date: March 7, 2005  
Page 5

#### REMARKS

Claim 1 is pending in this application. Claim 1 has been rejected. Claim 1 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the claim amendments and the following remarks.

#### **I. Specification**

The Examiner has pointed out certain typographical errors in the specification as filed. Applicant has amended the specification to correct those inadvertent errors. Withdrawal of the objection to the specification is respectfully requested.

#### **II. Rejection of Claims Under 35 U.S.C. §112, First Paragraph**

Claim 1 has been rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The Examiner acknowledges that the specification is enabling for a method of reducing pain characterized by an increase in monocyte chemoattractant protein-1 (MCP-1) levels, comprising administering to a mammal having said pain an effective amount of a MCP-1 neutralizing antibody or binding fragment thereof, thereby reducing pain in the mammal. However, the Examiner suggests that the specification does not provide enablement for a method of preventing pain or treating any type of pain in a mammal

Attorney Docket No.: DC-0301  
Inventors: DeLeo, Joyce A.  
Serial No.: 10/521,167  
Filing Date: March 7, 2005  
Page 6

comprising administering a MCP-1 antibody. Applicant respectfully traverses this rejection.

In an earnest effort to advance the prosecution and facilitate allowance of the claim, Applicant has amended claim 1 to recite that the method is a method of reducing neuropathic pain characterized by an increase in monocyte chemoattractant protein-1 (MCP-1) levels, comprising administering to a patient having said pain an effective amount of a MCP-1 neutralizing antibody or binding fragment thereof, thereby reducing neuropathic pain in the patient. Support for this amendment to the claim is found throughout the specification as filed and was acknowledged by the Examiner as being enabled by the teachings of the specification as filed. Accordingly, the claim as amended meets the requirements of 35 U.S.C. 112, first paragraph and withdrawal of this rejection is respectfully requested.

### **III. Rejection of Claims Under 35 U.S.C. 102(b)**

Claim 1 has been rejected under 35 U.S.C. 102(b) as being anticipated by Ogata et al. (1997). The Examiner suggests that this reference discloses that MCP-1 is involved in the pathogenesis of collagen-induced arthritis in rats and that rats injected with a MCP-1 antibody had reduced symptoms as compared to non-treated rats. The Examiner suggests that since the symptoms of arthritis-induced swelling are successfully treated, the reference would inherently treat the pain associated with arthritis. Applicants respectfully traverse this rejection. As discussed *supra*, the claim has been amended to recite that the method of the present invention is a method for reducing

Attorney Docket No.: DC-0301  
Inventors: DeLeo, Joyce A.  
Serial No.: 10/521,167  
Filing Date: March 7, 2005  
Page 7

neuropathic pain characterized by an increase in monocyte chemoattractant protein-1 (MCP-1) levels, comprising administering to a patient having said pain an effective amount of a MCP-1 neutralizing antibody or binding fragment thereof, thereby reducing neuropathic pain in the patient. Ogata et al. (1997) teach use of a neutralizing antibody against MCP-1 in rats to reduce the number of exudates macrophages in lesions produced in joints of the rats and to reduce the ankle swelling in the rats. The authors represent that MCP-1 plays a critical role in the rat model of arthritis in the recruitment of monocytes and the development of arthritis. Nowhere does this paper teach or suggest the reduction of pain of any type, including pain characterized by an increase in monocyte chemoattractant protein-1 (MCP-1) levels, comprising administering to an animal having said pain an effective amount of a MCP-1 neutralizing antibody or binding fragment thereof, thereby reducing pain in the animal. As discussed by the Examiner in the Office Action on page 5, "the art recognizes that different animal models of pain result in distinct neurochemical signature at the level of the spinal cord and afferent signaling pathways." Therefore, the present invention which claims in the amended claim a method for reducing pain specifically associated with an increase in MCP-1 levels and enabled by experiments showing that neuropathic pain is characterized by such increases, is not anticipated by a teaching of a reduction in the symptoms of swelling or arthritic lesions in joints (not spinal cord) of an animal, especially when no indice of pain was linked in the reference to any change

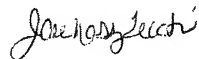
Attorney Docket No.: DC-0301  
Inventors: DeLeo, Joyce A.  
Serial No.: 10/521,167  
Filing Date: March 7, 2005  
Page 8

in MCP-1 levels. Further, as cited by the Examiner also at page 5 of the Office Action the art in this area "conclude that inflammatory [arthritis], neuropathic and cancer pain models each generate a unique and highly distinct set of neurochemical changes in the spinal cord and dorsal root ganglia..." MPEP 2131 states that in order to anticipate an invention the cited reference must teach each and every limitation of the claims. Clearly, the cited reference does not explicitly or even inherently teach the method of the present invention, particularly when the reference is considered within the context of what is known in the art regarding pain. Therefore, withdrawal of this rejection is respectfully requested.

#### IV. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



Jane Massey Licata  
Registration No. 32,257

Date: April 25, 2007  
Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
(856) 810-1515